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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,720	01/29/2002	Charles R. Vinson	2026-4199US3	7325

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

9

DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,720

Applicant(s)

VINSON ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The application has been transferred to Examiner Quang Nguyen in Art Unit 1636.

Claims 28-56 are pending in the present application.

Applicants' election with traverse the invention of Group II (claims 28-56) in Paper No. 8 is acknowledged.

However, upon reviewing the application the pending claims are subjected to the following new election/restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 28-37, drawn to a method of creating a transgenic plant utilizing a DNA molecule encoding an acidically modified nucleic acid binding protein containing an N-terminal extension of acidic amino acid residues, classified in class 800, subclass 278.
- II. Claims 28-56, drawn to a method of creating a transgenic nonhuman animal utilizing a DNA molecule encoding an acidically modified nucleic acid binding protein containing an N-terminal extension of acidic amino acid residues, and transgenic nonhuman mammal whose cells comprise a recombinant acidic dominant negative polynucleotide sequence and a method for producing the same transgenic nonhuman mammal, classified in class 800, subclasses 14, 21, for examples.

Claims 28-37 link patentably distinct inventions of Groups I and II that lack the unity of invention. This is because the method of creating a transgenic plant of Group I and the method of creating a transgenic nonhuman animal of Group II are distinct methods having different starting materials (plant cell vs nonhuman animal cell), different method steps and different technical considerations for achieving the end-results. Moreover, the end-results of these methods are different: a transgenic plant (Group I) and a transgenic nonhuman animal (Group II). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents. Additionally, as set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

A. Should Applicants elect the invention of Group I, further **Group Restriction** is required. Claims 28-37 link patentably distinction inventions that lack unity of invention. This is because Group I contains a plurality of distinct methods of creating transgenic plants containing a plurality distinct genes encoding expressible dominant negative proteins to naturally occurring cellular proteins comprising: (1) Fos; (2) Jun; (3) GCN4; (4) VBP; (5) GBF-1; (6) opaque; (7) DBP; (8) CHOP-10; (9) CREB; (10) C/EBP; (11) PAR; (12) ATF2; (13) c-myc; (14) n-myc; (15) l-myc; (16) max; (17) mad; (18) ID; (19) MyoD1; (20) E12; (21) AP-4; (22) TFE3; (23) USF; (24) FIP. Each of the aforementioned proteins has distinct amino acid sequence, different biochemical property/activity one from the others, and therefore the DNA molecule that encodes for

each of these acidically modified proteins to be utilized in a method for creating a transgenic plant is also distinct one from the others, and the phenotypes of the created transgenic plants using the different DNA molecule constructs are not necessarily the same. Therefore, the operation, function and effects of the methods creating a transgenic plant using different DNA molecules encoding distinct acidically modified proteins listed above are different and distinct. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicants must elect a specific protein listed above.

Additionally, further Group Restriction is required because claims 28-37 link patentably distinction inventions that lack the unity of invention. This is because Group I contains a plurality of distinct methods of creating transgenic plants containing a plurality distinct genes encoding expressible dominant negative proteins to naturally occurring cellular proteins, wherein the proteins comprise **distinct amino acid sequences listed in the Markush Group of claim 37.** Since the DNA molecule that encodes for each of the acidically modified proteins containing distinct amino acid sequences listed in the Markush group of claim 37 to be utilized in a method for creating a transgenic plant is distinct one from the others, and the phenotypes of the created transgenic plants using the different DNA molecule constructs are not necessarily the same, the operation, function and effects of the methods creating a transgenic plant using different DNA molecules are different and distinct. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and

(2) share a substantial structural feature disclosed as being essential to that utility.

Applicants must elect a specific SEQ ID NO listed in claim 37.

B. Should Applicants elect the invention of Group II, further **Group Restriction**
is required. Claims 28-41, 43-56 link patentably distinction inventions that lack the unity of invention. This is because Group II contains a plurality of distinct methods of creating transgenic animals or transgenic nonhuman mammals containing a plurality distinct genes encoding expressible dominant negative proteins to naturally occurring cellular proteins comprising: (1) Fos; (2) Jun; (3) GCN4; (4) VBP; (5) GBF-1; (6) opaque; (7) DBP; (8) CHOP-10; (9) CREB; (10) C/EBP; (11) PAR; (12) ATF2; (13) c-myc; (14) n-myc; (15) l-myc; (16) max; (17) mad; (18) ID; (19) MyoD1; (20) E12; (21) AP-4; (22) TFE3; (23) USF; (24) FIP. Each of the aforementioned proteins has distinct amino acid sequence, different biochemical property/activity one from the others, and therefore the DNA molecule that encodes for each of these acidically modified proteins to be utilized in a method for creating a transgenic animal or nonhuman mammal is also distinct one from the others, and the phenotypes of the created transgenic animals or nonhuman mammals using the different DNA molecule constructs are not necessarily the same. It is well known in the transgenic art that it is unpredictable to obtain any desired phenotype. Therefore, the operation, function and effects of the methods creating a transgenic animal or nonhuman mammal using different DNA molecules encoding distinct acidically modified proteins listed above are different and distinct. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a

common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicants must elect a specific protein listed above.

Additionally, further Group Restriction is required because claims 28-41, 43-56 link patentably distinction inventions that lack the unity of invention. This is because Group II contains a plurality of distinct methods of creating transgenic animals or nonhuman mammals containing a plurality distinct genes encoding expressible dominant negative proteins to naturally occurring cellular proteins, wherein the proteins comprise **distinct amino acid sequences listed as** SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:23, SEQ ID NO:25, SEQ ID NO:29, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:57, SEQ ID NO:64. Since the DNA molecule that encodes for each of the acidically modified proteins containing distinct amino acid sequences listed above to be utilized in a method for creating a transgenic animal or nonhuman mammal is distinct one from the others, and the phenotypes of the created transgenic animals or nonhuman mammals using the different DNA molecule constructs are not necessarily the same, the operation, function and effects of the methods creating a transgenic animal or nonhuman mammal using different DNA molecules are different and distinct. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicants must elect a specific SEQ ID NO listed above.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other for the reasons already set forth in the preceding paragraphs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements (e.g., different classification as well as different literature searches), it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Furthermore, a search of more than one of the listed SEQ ID NOs presents an undue burden on the Patent and Trademark Office. Therefore, restriction for examination purposes as indicated is proper.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.


PATENT EXAMINER